



DEPARTMENT OF HEALTH & HUMAN SERVICES

94582d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL **RETURN RECEIPT REQUESTED**

March 4, 2004

W/L 31-04

Lynell W. Braught
Chairman
Reality Health Research, Inc.
P.O. Box 337
Dolan Springs, AZ 86441

Dear Mr. Braught:

The Food and Drug Administration (FDA) has reviewed your web site at the following Internet address: www.realityhealthresearch.com. We have determined that the website labeling for several of your products violates the Federal Food, Drug, and Cosmetic Act (the Act) because it contains disease claims and/or unsubstantiated structure/function claims. You can find the Act and implementing regulations through links on FDA's Internet home page at www.fda.gov.

First, we have determined that several of your products are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the products are drugs because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (disease claims).

Examples of some of the claims observed on your web site include:

- CholesterLOW
 - This product's name is an implied claim that it reduces cholesterol.
 - "[A] natural way to safely and effectively reduce high blood cholesterol."
 - "The special liquid corn fiber we use has been proven to reduce the level of bad (LDL) cholesterol while increasing the good (HDL) cholesterol."
- Platinum
 - "Platinum is very important because it kills disease-causing bacteria, fungi, and viruses."

- “Because Platinum is a very strong natural anti-viral mineral, it is sometimes used in cancer treatments.”
 - “Some Symptoms of Deficiency: ...cancer, chronic fatigue”
- Selenium
 - “[T]here is evidence that it can help the body fight cancer.”
 - “Some Symptoms of Deficiency: ... Alzheimer’s, ... cancer, cardiomyopathy, cirrhosis of the liver, Cystic Fibrosis, ... heart disease, ... HIV (AIDS), ... Multiple Sclerosis, Muscular Dystrophy, ... Parkinson’s Disease, ... and sickle-cell anemia”
- Vanadium
 - “Vanadium is known to reduce cholesterol levels”
 - “Vanadium is known to lower elevated blood sugar readings, which is believed to help reduce the onset of heart attacks.”
 - “Some Symptoms of Deficiency: Cardio vascular disease, diabetes, high cholesterol, ... and obesity.”
- Chromium
 - “Some Symptoms of Deficiency: ... Attention Deficit Disorder, aortic cholesterol plaque, arteriosclerosis, bi-polar disease, coronary blood vessel disease, depression, diabetes, high blood cholesterol, ... obesity, ... and peripheral neuropathy.”
- Silver
 - “Water-soluble silver may be used internally to fight illness or infection.”
 - “Some Symptoms of Deficiency and Some Diseases Where the Use of Silver May be Beneficial: Anthrax, ... candida, cerebro-spinal meningitis ... diphtheria, diplococcus, dysentery, E. Coli, gonorrhea, impetigo, infection, influenza, pneumococci, ... shingles, staphylococci, tuberculosis, ... and whooping cough.”
- Gold
 - “Some Symptoms of Deficiency: Arthritis, ...cancer, ...depression, ... and obesity.”
- Indium
 - “Indium as a Treatment for Cancer”
 - “Indium is the only mineral known to naturally seek out and destroy cancer cells and cancerous tumors”

Because these products are not generally recognized as safe and effective for the above referenced conditions, they are also “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505 of the Act, a new drug may not be legally marketed in the United States without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. These drugs are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

Second, under section 403(r)(6) of the Act, a dietary supplement may include claims about the product’s effect on the structure or function of the human body (structure/function claims) [21 U.S.C. § 343(r)(6)(A)]. However, these “structure/function” claims must be truthful and not

misleading [21 U.S.C. § 343(r)(6)(B)]. The labeling of your Coral Calcium product bears structure/function claims, including the following from your web site:

- “When your pH is slightly alkaline, your body has the most ability to maintain good health. Only when you have enough calcium in the body will your pH be able to reach an alkaline state.”

We have reviewed this claim and have concluded that it is not supported by reliable scientific evidence. Because this claim lacks substantiation, it causes your Coral Calcium product to be misbranded within the meaning of sections 403(a)(1) and 403(r)(6) of the Act [21 U.S.C. § 343(a)(1), (r)(6)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. There may be other products and labeling, including product brochures or other promotional materials, distributed by your firm which have not been specifically described in this letter. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to do so may result in enforcement action without further notice, such as seizure and/or injunction.

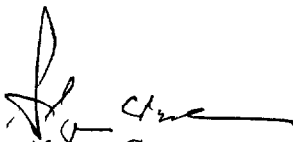
You should notify this office in writing within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

If you have any questions or need clarification regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer, at telephone number (949) 608-4439.

Your written reply should be directed to:

Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

Sincerely,



Alonza Cruse
District Director